

## VerifyNow Aspirin Platelet Reactivity Test INSTRUCTIONS FOR USE

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**INTENDED USE**  
The VerifyNow Aspirin Test is a qualitative test used to detect the detection of platelet dysfunction due to aspirin ingestion in patients with suspected aspirin-induced platelet dysfunction.

This test is not for use in patients undergoing concomitant platelet abnormalities, patients with non-aspirin induced acquired platelet abnormalities or in patients receiving non-aspirin anti-platelet agents (may be used in patients treated with selected COX-2 inhibitors, e.g., celecoxib (Celebrex)).

### PRODUCT DESCRIPTION

The VerifyNow System is a semi-automated optical detection system which measures platelet induced aggregation. The VerifyNow System consists of an instrument, a disposable test device and quality control materials. See Figure 1 for a representation of the test device. Quality control measures include an instrument based electronic quality control (ECC), two levels of wet quality controls (WQC), and internal quality controls. The instrument based ECC monitors the performance of the VerifyNow Test. The WQC and internal quality controls are used to complete the test if the degree of platelet function is determined and the result is displayed. The device contains a lysis/lyophilized preparation of human fibrinogen-coated beads, platelet agonist, and buffer. The whole blood patient sample is taken from the blood collection tube by the device by its instrument, without any hand handling required by the user.

**PRINCIPLE**  
Aspirin affects platelet function by irreversibly blocking the cyclooxygenase (COX-1) enzyme involved in the conversion of arachidonic acid to thromboxane A<sub>2</sub>, which inhibits platelets from GMP release and is involved in platelet aggregation. If aspirin has produced the expected anti-platelet effect, such aggregation will not occur. The VerifyNow Aspirin Test incorporates the agonist arachidonate acid to activate platelets. The Aspirin Test is designed to measure platelet function based on the ability of activated platelets to bind fibrinogen. Fibrinogen-coated platelets are added to a whole blood sample. The degree of aggregation is measured by the degree of platelet desorption as measured by the fibrinogen coated bead count in the blood collection tube by the device by its instrument, without any hand handling required by the user.

**MATERIALS PROVIDED**  
• One VerifyNow Aspirin Test kit (25) | PN: 454322 VerifyNow Aspirin Test devices, individually sealed in foil pouches. Each test device contains a lyophilized fibrinogen-coated platelet agonist, peptide, bovine serum albumin, stabilizer, and buffer.

**REAGENT SOURCE AND HANDLING**

• Test Device Kit Indication: VerifyNow Aspirin Test is a semi-automated test of the reagent of the packaging. The Test Device Kit Indication is used to indicate the source of the reagent.

• Store test devices at 2-25°C (36-77°F).

• If refrigerated, allow test devices to reach room temperature 18° to 25°C (64°-77°F) prior to use.

• If refrigerated, allow test devices to reach room temperature 18° to 25°C (64°-77°F) prior to use to prevent damage by humidity.

**TEST REQUIREMENTS BUT NOT PROVIDED**

• Greiner Bio-One Vacutainer® 2 ml blood collection tubes containing 3.2% sodium citrate. Greiner Catalog # 454322 or Nunc catalog #NP-CW0185-1 blood collection tubes (1.8ml) containing Sodium Citrate (3.2%).

• VerifyNow Instrument with Electronic Quality Control (ECC).

• VerifyNow WQC Catalog #W5047.

**GENERAL PRECAUTIONS**

• For in vitro diagnostic use.

• The VerifyNow System Test devices or components should only be used as directed in the User Manual.

• Do not use VerifyNow Aspirin Test devices or components for any purpose other than to prevent damage by humidity.

• All reagents should be stored at 2-25°C (36-77°F) until opened.

• All reagents should be discarded after 6 months from the date of manufacture.

• All reagents should be discarded if they have passed their expiration date.

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